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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Pachl, et al.	}	Attorney Docket No. 9134-0414
Title: COATED TEST ELEMENTS	}	Examiner: Lyle Alexander
Serial No.: 10/581,409	}	Confirmation No. 3752
Filed: September 20, 2006	}	Art Unit: 1773

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Martin Frank, hereby declare that:

1. I am a joint inventor ("inventor") of the pending claims of the above-identified application.

2. I hereby incorporate herein by reference my earlier Declarations executed on July 28, 2011 and August 19, 2011, which were earlier submitted in the above-identified application.

3. I understand that the Office Action having a mailing date of October 7, 2011 states that if my Declaration is "read as submitted with an Exhibit/photograph that show the difference between examples 3a and 3c, the art of record may be overcome."

4. Therefore, I submit herewith as Exhibit A high quality photographs which were used to prepare Figs. 3a-3c of the above-identified application. The photos shown in Exhibit A are true and accurate photos of test elements that were tested as described in

the instant application. I have therefore labeled the photographs in Exhibit A as Figs. 3a-3c. My explanation of the photographs in Exhibit A and comments are as follows:

a. Test elements were produced according to WO 99/29429. These test elements are multi-layered and have an opening centered at the bottom edge of the elements as shown in the photos in Exhibit A. The opening extends into a capillary channel, which terminates in a test region.

b. In accordance with the teachings of our invention, the test elements shown in Fig. 3a of Exhibit A were coated on the outside with a lotus effect spray. In particular, the surface of the carrier foil of the test elements was coated with hydrophobic nanoparticles to form a hydrophobic structure with elevations and depressions, the height of the elevations ranging from about 50 nm to 100 μm. This treatment provides a hydrophobic structured surface around the application zone. The test elements were then immersed in a 10 μl drop of blood. After the test elements were removed from the sample, no blood could be seen in the area of the test elements surrounding the opening. This is consistent with the photo labeled Fig. 3a of the attached Exhibit A.

c. It can be clearly seen from the photos in Exhibit A that there is no blood visible in the area surrounding the channel openings on any of the test elements shown in Fig. 3a. It appeared from my observations that the hydrophobic structured surfaces we formed prevented blood from adhering to the area surrounding the opening and instead guided the blood sample into the channel.

d. The same type of test elements are shown in Fig. 3b of Exhibit A. Instead of being formed with a lotus effect surface in accordance with the instant invention, however, a standard wax with known hydrophobic properties was used as a coating. These test elements were immersed in a 10 μml drop of blood and then removed, as described above. It can be seen in Fig. 3b of Exhibit A that the blood sample spread and contaminated areas around the channel opening on all of the test elements shown in Fig. 3b of Exhibit A.

e. The test elements shown in Fig. 3c of Exhibit A were treated with a Teflon spray in the area surrounding the opening, but are otherwise the same as the test elements shown in Figs. 3a and 3b. These test elements were immersed in a 10 µml drop of blood and then removed, as described above. While the spreading of blood contamination on the samples of Fig. 3c was not as great as in the test elements of Fig. 3b, blood contamination of some portion of the area surrounding the channel opening can be clearly seen in all test elements shown in Fig. 3c in the attached Exhibit A.

5. For further background on the advantages of the present invention as claimed, I submit the following:

a. Disadvantages of Known Devices

With known blood glucose test strips, particularly capillary test strips which are considered to be self-dosing, excess blood sample typically adheres to the outside of the strip surrounding the capillary after the strip is used. When the test strip is disposed of, this blood, depending on the point of disposal, constitutes a risk of contamination and presents a hygiene problem. The current aim for blood glucose measuring systems I am developing is to increase integration of the handling steps and the individual parts of the system. In one device the test strips are automatically reshelved. That is, the test strip is pulled back into a drum through a strip guide, past the optics of the instrument. As the test strip travels through the device, the blood on the outside of the strip constitutes a risk of contamination of the measuring device.

Fresh blood being transported through the device is not the only contamination problem. Additionally, during the re-shelving of the test strips, it has been shown that blood which has dried on the outside of the test strips can fall off and contaminate parts of the device, the optics and the environment. A method which prevents the contamination of the outside of test strips with blood would therefore be an improvement, especially for capillary systems.

Unfortunately, known methods of attempting to achieve hydrophobicity have proven insufficient.

b. The Instant Invention

A coating with hydrophobic nanoparticles, known as lotus effect materials, provides the necessary hydrophobicity, chemical inertness and immunity against spreading of material. As discussed above, this coating produces a hydrophobic structured surface comprising elevations and depressions, the height of the elevations ranging from about 50 nm to 100 μm. This hydrophobic structured surface creates an extremely large contact angle of up to 160° compared with aqueous systems and eliminates contamination of such surfaces from blood. The remarkable and surprising results can been seen with reference to Fig. 3a of the photos attached hereto.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Martin Frank

Martin Frank

03-Feb-2012

Date

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